

PMW FLOCKED SWAB

1. 제조원

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2. 신고번호 : 제신 20-847호

3. 제품명 : PMW Flocked Swab

4. 모델명 : PMW-SWAB NP1 | PMW-SWAB OP2 | PMW-SWAB DUAL | PMW-NS SWAB

5. 제품구성

모델명	구성
PMW-SWAB NP1	1 EA
PMW-SWAB OP2	1 EA
PMW-SWAB DUAL	NP1 1 EA + OP2 1 EA 로 총 2 EA 1 SET
PMW-NS SWAB	1 EA

6. 사용 목적

질병 검사 등을 위하여 짧은 시간 안에 구강, 비강, 이강 또는 항문에서 체액, 분비물 등을 채취하는 도구.

7. 사용방법

① 사용 전 준비사항

- 사용 전 제품 포장의 이상 여부와 제품의 손상, 파손을 확인한다.

② 사용방법

1) 제품을 개봉한다.

2) 제품을 포장지로부터 조심스럽게 꺼낸다.

3) 환자로부터 검체를 채취한다.

4) 별도의 보관 또는 운반 용기에 제품의 헤드부를 넣고, Break Point 부분에 힘을 가한다.

(보관 또는 운반 용기가 클 경우 제품의 전체를 넣는다.)

(PMW-NS SWAB의 경우 : 별도의 운반 용기에 채취된 검체 채취도구를 넣는다.)

③ 사용 후 보관 및 관리방법

1) 본 제품은 일회용이므로 사용 후 반드시 폐기한다.

2) 재사용 금지

8. 사용 시 주의사항

① 경고

1) 본 제품은 일회용 제품으로 재사용을 금지한다.

2) 본 제품은 포장이 파손되었을 경우 사용하지 않는다.

3) 본 제품을 수직으로 구부려 사용하지 않는다.

② 사용 시 주의사항

1) 사용하기 전에 제품의 손상이 없는지 확인한다.

2) 검체 채취 시 많은 힘을 가하거나 강하게 누르는 등의 과도한 힘이 가해지지 않도록 주의하여 사용한다.

3) 직사광선을 피하고 실온 보관한다.

4) 검체 채취 시 수직으로 구부려 사용할 경우 브레이크 포인트가 부러질 수 있으므로 주의하여 사용한다.

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Device Name

Product Name: PMW Flocked Swab

Model Name: PMW-SWAB DUAL, PMW-SWAB NP1, PMW-SWAB OP2, PMW-NS SWAB

General Description

The flocked swabs feature perpendicular nylon(to use flocking swab) and PET(to use throat swab) fibers that optimize specimen collection. The swabs also feature a molded breakpoint that allows you to safely and easily break off the swabstick, and several breakpoint options are available.

Intended Purpose

A nasopharyngeal or oropharyngeal swab is a method for collecting a clinical test sample of nasal or throat secretions from the back of the nose and throat. The sample is then analyzed for the presence of organisms or other clinical markers for disease.

Performance Characteristics

PMW Flocked Swab is a specimen collection swab that has a tip flocked with soft nylon fiber. The nylon flocked specimen collection swabs have a solid plastic shaft with a molded breakpoint site.

To collect the sample, the swab is inserted in the nostril and gently moved forward into the nasopharynx, a region of the pharynx that covers the roof of the mouth. The swab is then rotated for a specified period time to collect secretions, then the swab is removed.

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Indications

The swab is suitable for short contact with nasopharyngeal and oropharyngeal of the human body.

Contra-indications

There are no known specified contraindications.

Patient Target Group

Age	Not relevant	Weight	Not relevant	Nationality	Not relevant
Gender	Not relevant	Health	Not relevant	Patient State	Not relevant

Intended Users

This medical device is intended to be used only by healthcare professionals such as doctors and medical personnel (e.g., research nurse or physician)

Residual Risks

There is no residual risk with this medical device after conducting risk management activities.

Precautions and warnings

- This product is disposable and reuse is strictly prohibited.
- This product should not be used if the package is damaged or opened.
- Do not use if expired expiration date.
- It should be used only for intended purpose.
- Do not use the device perpendicularly. Please use the device in an oblique direction.

Attention

- Take care as this may break if excessive force is applied during specimen collection.
- If this product is exposed to chemical and physical sterilization or micro-biostatic process, its intended performance may not be achieved.
- User should fully aware of usage before use.

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- When handling specimen, be sure to have protective equipment to avoid any risk of infection and tested in accordance with bio-safety guidelines.
- Do not use unless peel-pouch is intact.
- Please be aware that the head part should not be touched.
- It should be disposed in a disposal box after used.
- Please be aware of using the device perpendicularly, the break point of the device may break during use if the user uses the device perpendicularly.

Undesirable Side-effects

The tip of the device may break during use, and the patient may swallow the broken part with the specimen. While collecting the specimen by using a Nasopharyngeal swab, it can break and move to the back of the nose.

Preparatory Treatment or Handling

- Storage at room temperature(1~30°C) as of sealed status.
- Check the sealed status if damaged or abnormalities and product damage before use and do not use if the package is damaged or opened.
- Check the expiration date of the product before use and do not use if expired.
- User should fully understand how to use this product.
- Wear gloves to prevent any infection.

Storage Condition

Storage temperature: Room temperature (1~30°C)

Shelf-life (Life time)

3 years from the date of manufacture

Single Use

This medical device is intended for single use.

Information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used

- There is a risk of infection if the device is reused.

Information for Safe Disposal

This device is disposable for single use only.

Once used, it must be disposed of in accordance with the regulations, and reuse is prohibited.

Wear gloves to prevent any infection.

It should be disposed in a disposal box after used.

Notice to Users/Patients

Any serious incident that has occurred in relation to this medical device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Product Components

No.	Model	Contents
1	PMW-SWAB DUAL	Total two swabs are included in one blister packaging. NP1 is intended to collect specimens from the nasopharyngeal, and OP2 is intended to collect specimens from the oropharyngeal.
2	PMW-SWAB NP1	A swab that is intended to collect specimens from the nasopharyngeal is included in one blister packaging.
3	PMW-SWAB OP2	A swab that is intended to collect specimens from the oropharyngeal is included in one blister packaging.
4	PMW-NS SWAB	A swab that is intended to collect specimens from the oropharyngeal is included in one blister packaging.

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How to Use

Any serious incident that has occurred in relation to this medical device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



- ① Peel off the sealed film package then, pull the product out after grab the body handle.
- ② Collecting specimen from the mouth, nasal cavity, ear or anus. In order to reduce the possibility of other contamination, the TIP part of the head is in contact with the suspected infection area quickly.
- ③ Rotate the body handle a few times to ensure that the specimen are effectively collected to the head end.

Symbols of Packaging

	CE marking		Medical Device		Manufacturer
	Authorized representative in the European Community		Date of manufacturer		Use-by date
	Lot Number		Catalogue Number		Do not use if package is damaged
	Temperature limit		Do not re-use		caution



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